K003769

Ansell
PROFESSIONAL HEALTHCARE

DEC 22 2000

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Encore® MicrOptic® Powder Free Latex Surgical Gloves (Protein Label Claim)
Ansell
1875 Harsh Avenue SE
Massillon, Ohio 44646
Telephone: 330-833-2811
Fax: 330-833-6501

[1] Summary

[2] Ansell
1875 Harsh Avenue SE
Massillon, Ohio 44646

Contact: James R. Chatterton
Telephone: 330-833-2811
Fax: 330-833-6501

December 1, 2000

[3] Trade Name: Encore® MicrOptic® Powder Free Latex Surgical Gloves (Protein Label Claim) 50 MICROGRAMS OR LESS)
Common Name: Surgical Gloves
Classification Name: Surgeon's Glove

[4] Encore® MicrOptic® Powder Free Latex Surgical Gloves (Protein Label Claim) meet all of the requirements of ASTM D 3577-00, Type 1.

[5] Encore® MicrOptic® Powder Free Latex Surgical Gloves (Protein Label Claim) meet all the current specifications for ASTM D 3577-00 Rubber Surgical Gloves.

[6] Encore® MicrOptic® Powder Free Latex Surgical Gloves (Protein Label Claim) are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

[7] Encore® MicrOptic® Powder Free Latex Surgical Gloves (Protein Label Claim) are summarized with the following technological characteristics compared to ASTM or equivalent standards.

| Characteristics | Standard |
|---|---|
| Dimensions | Meets ASTM D 3577-00 |
| Physical Properties | Meets ASTM D 3577-00, Type 1 |
| Freedom from holes | Meets ASTM D 3577-00<br>Meets ASTM D 5151-99 |

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| | |
|---|---|
| Protein Label Claim | This latex glove contains 50 micrograms or less of total water extractable protein per gram.<br><br>Meets ASTM D 5712-99 Standard Test Method for Analysis of Protein in Natural Rubber and Its Products |
| Biocompatability | |
| Primary Skin Irritation in Rabbits | Passes |
| Guinea Pig Sensitization | Passes |

[8] The performance test data of the non clinical tests are the same as mentioned immediately above.

[9] Clinical data is not needed for medical gloves or for most devices cleared by the 510(k) process.

[10] It is concluded that the Encore® MicrOptic® Powder Free Latex Surgical Gloves (Protein Label Claim) are as safe, as effective, and perform as well as the glove performance standards referenced above and therefore meet:

ASTM listed standards,
FDA hole requirements, and
labeling claims for the product.

[11] This summary will include any other information reasonably deemed necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

Mr. James R. Chatterton
Vice President Regulatory
Ansell Healthcare Products, Incorporated
1875 Harsh Avenue Southeast
Massillon, Ohio 44646

Re: K003769
Trade Name: Encore Microptic Powder-Free Latex Surgical Gloves With Protein Content Labeling Claim ( 50 micrograms or less )
Regulatory Class: I
Product Code: KGO
Dated: December 1, 2000
Received: December 6, 2000

Dear Mr. Chatterton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

## Indications for Use Statement

510(k) Number (If known): K003769

**Device Name:** ENCORE MICROPTIC POWDER-FREE LATEX SURGICAL GLOVES WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)

**Indications for Use:** Encore® MicrOptic® Powder Free Latex Surgical Gloves intended use is to be worn by operating room personnel to protect a surgical wound from contamination.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ___/___
Per 21 CFR 801.109

Barbara for Chin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003769